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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,628	06/22/2001	Vincent Chiang	15164.47	7405

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,628	CHIANG, VINCENT	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-24 are pending. Claims 1-20 are considered on the merits. Claims 21-24 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

Claims 11, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11- sodium acetate is not a sodium ion. It may be the source of sodium ions, but sodium acetate is not a sodium ion.

Likewise for claims 19 and 20.

Claim Rejections - 35 USC § 102

Claims 12-17 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 01-181799 [O].

The claims are directed to a composition comprising:
α-amylase Ca^{+2} free,
a sodium ion,
a detecting substrate, wherein the composition is substantially free of Cl^- and wherein the α-amylase is capable of being activated by the sodium ion in proportion to the amount of Cl^- in the sample.

JP 01-181799 discloses on page 5, lines 5-15 of the translation, a first composition comprising:

α-amylase substantially Ca^{+2} free (that is in the inactive form) page 2 of the translation,

Ca^{2+} chelated with EDTA,

EDTA,

phosphate buffer brought to pH 7 with NaOH, (a source of sodium ions),

and a second composition comprising:

2-chloro-4-nitrophenyl-β-D-maltoheptaoside.

The two reagents are combined in the performance of the assay.

Response to Arguments

Applicant's arguments filed 11/6/03 have been fully considered but they are not persuasive.

Applicant argues that the phrase "wherein the α-amylase is activated by the sodium ion in proportion to the amount of the chloride ion in the fluid sample" distinguishes the composition from the prior art. However, this phrase is an intended use phrase and as such is not read as a component of the composition. Further this phrase does not appear in the claim language. Rather, the language "capable of being activated" is present. In the absence of evidence to the contrary, the α-amylase of the prior art is considered to be CAPABLE OF BEING ACTIVATED BY THE SODIUM ION...". Capability is an inherent property of the enzyme. Since it is the same enzyme as the enzyme of the claimed composition, it is considered to possess all of the inherent properties of the enzyme. Applicants argue that the claimed composition is not comprised in the same way as the prior art composition. However, the composition AS CLAIMED is the same. Compositions have components. If the components are not the same as those of the prior art, then the compositions are distinguished.

Claim Rejections - 35 USC § 103

Claims 1-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-181799 [O].

JP 01-181799 discloses a method of assaying Cl^- concentration comprising:

preparing a composition containing
α-amylase which is substantially Ca^{+2} free, that is, in the inactivated form,
disodium EDTA, NaOH,
Ca^{+2}EDTA,

combining it with the α-amylase activity detecting substrate which is in a 0.1M sodium phosphate buffer,

and the Cl^- sample and determining the α-amylase activity which is correlated with Cl^- concentration.

The concentration of Na^+ in the 0.1M sodium phosphate buffer at pH 7 is, at the very least, 0.1M, and the concentration of Cl- in the sample, which is a NaCl solution, is at the very most 0.2M. Thus, the concentration of Na^+ is clearly greater than the concentration of Cl^- as is required by the claim.

The α-amylase has been rendered Ca^{2+} free by use of calcium ion chelating compounds such as EDTA (p. 4, l. 16).

The specific exemplified α-amylase substrate is 2-chloro-4-nitrophenyl-β-D maltoheptaoside, but any known substrate may be used (end of page 3 of the translation).

Chloride ion determinations may be performed in bodily fluids such as blood (page 6 of translation).

Response to Arguments

Applicant's arguments filed 11/6/03 have been fully considered but they are not persuasive.

Applicant argues that the Na+ used in JP 01-181799 is not used as an activator but merely to balance pH. First, Na+ cannot be used to balance pH as it is pH neutral. NaOH, however is not pH neutral. Second, the intended use or

the mechanism of a reaction is of little patentable weight when all the active steps of the method and the compositions used in the method appear to be the same as those in the prior art. If a disclosed method anticipates or makes obvious the claimed method, even though the underlying mechanism is not understood at the time of the prior art, the disclosure may anticipate or make obvious by inherency. Whether the disclosure is made "by chance" is not relevant to either its patentability or its value as prior art.

Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or ***processes,*** regardless of whether or not they

understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Methods have active steps and use specific compounds/compositions to achieve the desired results. Methods are the same if they have the same active steps and use the same compounds/compositions to measure the same substrate regardless if the underlying mechanisms are understood or not.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-181799 [O] and JP 11-266898 [P].

The claim is directed to the inclusion of 2-chloro-4-nitrophenyl-α-D-maltotrioside in the composition.

The references are relied upon as explained below.

JP 01-181799 on page 3 suggests that other compounds conventionally used may be substituted for the specifically listed α-amylase substrates.

JP 11-266898 teaches that 2-chloro-4-nitrophenyl-α-D-maltotrioside is a suitable compound for use in measuring α-amylase activity.

The substitution of 2-chloro-4-nitrophenyl-α-D-maltotrioside for 2-chloro-4-nitrophenyl-β-D-maltoheptaoside in the composition of JP 01-

181799 would have been obvious when the primary reference was taken with JP 11-266898 because JP 01-181799 suggests that any suitable substrate for the detection of α-amylase activity may be used and JP 11-266898 demonstrates that 2-chloro-4-nitrophenyl-α-D-maltotrioside is such a suitable substrate.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

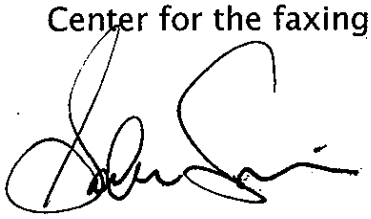
Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. **Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198.** The number of the Fax Center for the faxing of official papers is (703) 872-9306.



Sandra Saucier
Primary Examiner
Art Unit 1651
December 30, 2003